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MYERS, CARLA J	
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09819091	2/16/00	CAO ET AL.	16517.124

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EXAMINER
Carla Myers

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/819,091
Filing Date: February 16, 2000
Appellant(s): CAO ET AL.

Gautam Prakash, Holly L. Prutz, and David R. Marsh
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 30, 2007 appealing from the Office action mailed October 30, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

(a) Serial No. 09/619,643; Board of Patent Appeals and Interferences No. 2002-2046; Federal Circuit Case No. 04-1465; Ex parte Fisher, 72 USPQ2d 1020 (Board of Patent Appeals and Interferences 2004); In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005),

(b) U.S. Application Serial No. 10/437,963,

(c) U.S. Application Serial No. 09/684,016,

(d) U.S. Application Serial No. 10/361,942,

(e) U.S. Application Serial No. 09/199,129,

(f) U.S. Application Serial No. 09/920,953,

(g) U.S. Application Serial No. 09/663,423,

(h) U.S. Application Serial No. 09/654,617; Appeal 2003-1744, decided June 30, 2004, Examiner Affirmed, and

(i) U.S. Application Serial No. 09/619,643; Appeal No. 2002-2046, decided March 31, 2004, Examiner Affirmed.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Sparks et al. Proceedings of the National Academies of Sciences. 1996. 93: 1540-1544.

Whisstock et al. Quarterly Reviews of Biophysics. 2003. 36: 307-340.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. Claim Rejections - 35 USC § 101 (Utility)

Claims 1 and 8-11 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific or well-established utility.

The claims are drawn to substantially purified nucleic acid molecules having the sequence of SEQ ID NO: 1 and to substantially purified nucleic acid molecules comprising a nucleic acid sequence having 90% to 100% identity to SEQ ID NO: 1.The claimed nucleic acids are not supported by either a specific and substantial asserted utility or a well-established utility.

The specification discloses nucleic acids consisting of SEQ ID NOs. 1-51,470. Each of these nucleic acids was isolated from a library prepared from *Arabidopsis thaliana* tissue. The present claims are limited to nucleic acids comprising SEQ ID NO: 1 and nucleic acids having 90-100% identity with SEQ ID NO: 1.

The specification does not set clearly forth a particular biological activity of a putative protein encoded by SEQ ID NO: 1. In Table 1 (page 92), it is stated that the nucleic acid of SEQ ID NO: 1 shares 84% identity with a nucleic acid encoding an "unknown protein with Src homology 3 (SH3) domain profile." There is no showing that the protein encoded by SEQ ID NO: 1 does in fact contain a SH3 domain profile. The recitation that SEQ ID NO: 1 shares identity with nucleic acid encoding a protein having a SH3 domain profile is not equivalent to a clear statement that the protein encoded by SEQ ID NO :1 has the same biological activity of the "unknown protein." Even if it is determined that the protein encoded by SEQ ID NO: 1 has a SH3 domain profile, the specification has not established that the presence of the SH3 domain profile imparts a specific biological activity to the encoded protein. Proteins having SH3 domains are significantly diverse with respect to the ligands that they bind and with respect to their overall functional activities. Thereby, the finding that a protein has a SH3 domain or shares identity with a protein having an SH3 domain does not apprise one of skill in the art of a specific biological activity associated with said protein.

No specific biological activity has been disclosed for the "unknown protein" to which the presently encoded protein shares sequence identity. Even if a specific biological activity was provided for this protein, the classification of a protein based on

amino acid sequence homology does not establish a specific and substantial use for the nucleic acids encoding that protein. Sequence and structural homology between different nucleotide and amino acid sequences are not necessarily correlated with functional activity since proteins having SH3 domains may have very distinct biological activities. For example, Whisstock et al (see abstract) teaches that "...prediction of protein function from sequence and structure is a difficult problem, because homologous proteins often have different functions. Many methods of function prediction rely on identifying similarity in sequence and/or structure between a protein of unknown function and one or more well-understood proteins. Alternative methods include inferring conservative patterns in members of a functionally uncharacterized family for which many sequences are known. However, these inferences are tenuous. Such methods provide reasonable guesses at function, but are far from foolproof."

The specification (page 39) states that the claimed nucleic acids can be used to obtain other nucleic acids from the same species or to isolate homologous nucleic acids from other species. However, such uses lack a specific and substantial utility. Such uses allow only for the identification and analysis of other nucleic acids which in turn will also lack a specific and substantial utility in the absence of any specific function or activity attributed to the protein encoded by SEQ ID NO 1. Because a utility has not been established for the present nucleic acid, the use of this nucleic acid to search for additional nucleic acids does not constitute a "real world" context of use.

The specification (page 39-40) further contemplates that the nucleic acid of SEQ ID NO: 1 can be used for mapping studies, linkage analysis, constructing transgenic

plants, screening for traits or screening for polymorphisms. However, these uses are applicable to a broad class of molecules since all plant nucleic acids could be used for these purposes. Thereby, these uses are general and do not constitute a specific utility. While the use of the nucleic acid of SEQ ID NO: 1 in the disclosed methods may eventually lead one to the identification of useful traits or specific polymorphisms or may eventually allow for the generation of transgenic plants, such uses constitute further research and experimentation and do not provide a readily-available, specific and substantial real-world use.

The specification (page 79) asserts that the nucleic acid of SEQ ID NO: 1 can be used for antisense methods to "prevent or reduce gene function." However, since it is unclear as to the activity of the nucleic acid of SEQ ID NO: 1 and the protein encoded by SEQ ID NO: 1, the use of the claimed nucleic acids to block or prevent an unknown function constitutes further research. Thereby, the use of the claimed nucleic acids for antisense methods does not provide a substantial, real world use for the claimed nucleic acids.

The specification contemplates that the nucleic acid of SEQ ID NO: 1 can be used to synthesize protein, which could then be used in conducting further research to characterize the protein. However, the need for such research clearly indicates that the protein is not provided in a form that can be currently utilized for a real world purpose. Identifying and studying the properties of a protein or the mechanisms in which the protein is involved does not constitute a specific and substantial utility.

The specification also suggests that the proteins encoded by the nucleic acid of SEQ ID NO: 1 could be used to generate antibodies which could be used for detection purposes. Again, because a utility has not been established for the nucleic acid or the protein encoded thereby, use of the protein to generate antibodies to isolate and study proteins constitutes a research project and does not provide a specific and substantial utility.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement as it applies to nucleic acids. See In re Fisher 421 F.3d 1356, 76 USPQ2d 1225 (Fed. Cir. 2005). The Court held that 35 USC 101 requires a showing that a nucleic acid is both substantial and specific, stating that "not every 'use' that can be asserted will be sufficient to satisfy §101. " The court emphasized that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some further date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that claimed invention has a significant and presently available benefit to the public." Id. 76 USPQ2d at 1230.

The Fisher Court also held that none of the uses asserted by Appellants in that case were either substantial or specific because each of the "asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." The Court concluded that "granting a patent to Fisher for its five claimed ESTs would amount to a hunting license because the claimed ESTs can be used only to gain

further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of Fisher's research effort, but only tools to be used along the way in the search for a practical utility."

The instant situation is analogous to that which was addressed in Fisher. Appellants have not established that the claimed nucleic acid encodes for a protein with a specific and substantial biological activity, or that the nucleic acid or protein could be used to identify a particular trait or to detect a particular polymorphism or promoter of known function. Accordingly, the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

B. Claim Rejections - 35 USC § 112 – (Enablement)

Claims 1 and 8-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Further, the claimed invention is not enabled because the function of the nucleic acid of SEQ ID NO: 1 cannot be reliably predicted on the basis of a statement in the specification indicating that SEQ ID NO: 1 shares sequence identity with a nucleic acid having SH3 domains, but having no known biological function. As discussed above, the presence of a SH3 domain does not impart a specific and substantial biological activity onto a protein because proteins having SH3 domains are significantly diverse with respect to the ligands that they bind and with respect to their overall functional activities.

Additionally, the function of a nucleic acid cannot be reliably predicted on the basis of its amino acid sequence alone. As discussed by Whisstock et al. (see abstract):

"...prediction of protein function from sequence and structure is a difficult problem, because homologous proteins often have different functions. Many methods of function prediction rely on identifying similarity in sequence and/or structure between a protein of unknown function and one or more well-understood proteins. Alternative methods include inferring conservative patterns in members of a functionally uncharacterized family for which many sequences are known. However, these inferences are tenuous. Such methods provide reasonable guesses at function, but are far from foolproof."

Whisstock (page 311-312) further teaches that while information regarding a proteins sequence, structure, genomics and interaction patterns may be useful in guiding experimental investigations into protein function,

"...inferring protein function from knowledge of the function of a close homologue is like solving the clue of an American crossword puzzle. Finding the word that satisfies the definition may be difficult but the task in principle is straightforward. Working out the function of a protein from its sequence and structure is like solving the clue of a British crossword puzzle. It is by no means obvious which features of the definition are providing the real clues, as opposed to misleading ones. Also, for both types of puzzle and for the suggestion of a protein function, even if your answer appears to fit it may be wrong."

Regarding claims 8-11, the specification has not adequately taught one of skill in the art how to use nucleic acids which comprise a nucleic acid sequence which has 90% to less than 100% identity with SEQ ID NO: 1. Claims 8-11 encompass nucleic acids comprising a nucleic acid sequence having 90%-99.9% identity with a nucleic acid sequence of SEQ ID NO: 1. Since the claims allow for sequence variation within the nucleic acid molecule, the claims include nucleic acids from species other than *Arabidopsis thaliana*, naturally-occurring and non-naturally occurring mutated nucleic acids, allelic variants, and splice variants. The specification has not adequately taught

one of skill in the art how to use a representative number of species within this genus of nucleic acids. It is unpredictable as to what would be the functional activity of nucleic acids having 90% to 99.9% identity with SEQ ID NO: 1. It is well known that for nucleic acids, as well as for proteins, even a single nucleotide or amino acid change can destroy the function of the molecule in many instances, albeit not in all cases. The effect of a nucleotide or amino acid change is largely unpredictable. In the absence of extensive information regarding the relationship between the structure and function of the molecule, one cannot determine a priori which nucleotide or amino acid changes will effect functional activity and which will not. Therefore, the recitation of sequence similarity results is an unpredictable and thus unreliable correspondence between the claimed nucleic acid and the reference nucleic acid. The specification has not established that species within this genus of nucleic acids have any particular biological activity and the specification has not provided sufficient guidance as to how to use a representative number of species within the claimed genus of nucleic acids without undue experimentation.

C. Claim Rejections - 35 USC § 112 (Written Description)

Claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

In analyzing the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note that with regard to genus/species situations, a "Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the Appellant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

To ascertain whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. It is then determined whether a representative number of species have been defined by other identifying characteristics.

In the present situation, the claims are drawn to substantially purified nucleic acids comprising a sequence having between 90% to 100% identity to a nucleic acid sequence of SEQ ID NO: 1. The nucleic acids are not defined in terms of any particular functional properties. The claims thereby encompass variants of SEQ ID NO: 1, including mutants, allelic and splice variants of SEQ ID NO: 1 and homologues of SEQ ID NO: 1 from non-*Arabidopsis thaliana* species (see pages 31-32 of the specification). Since no functional activity is set forth for the nucleic acids, the nucleic acids may have functional activities substantially distinct from SEQ ID NO: 1. Thereby, the claims encompass a potentially very large genus of nucleic acids. However, the specification

describes only one nucleic acid within the claimed genus by its complete structure – i.e., the nucleic acid of SEQ ID NO: 1.

No additional members of the claimed genus have been sufficiently described in terms of any other relevant identifying characteristics (e.g. restriction map, biological activity of an encoded protein product, etc.).

Thus, Appellant has established possession of only one member of the claimed genus, the nucleic acid of SEQ ID NO: 1.

Further, the specification does not disclose a clear structure-function relationship for the claimed nucleic acids. The specification (Table 1, page 92) teaches that the nucleic acid sequence of SEQ ID NO: 1 shares 84% identity with a nucleic acid encoding an "unknown protein with Src homology 3 (SH3) domain profile." However, the specification has not established that the protein encoded by SEQ ID NO: 1 itself has a SH3 domain profile. Further, it has not been established that the presence of the SH3 domain profile imparts a specific biological activity to the protein encoded by SEQ ID NO: 1. No additional information is provided regarding the overall functional properties of SEQ ID NO: 1. In particular, the specification does not identify the location of any particular domains or sequences within SEQ ID NO: 1 which are required to impart a particular function.

The general knowledge in the art concerning homologues, mutants, allelic and splice variants does not provide any indication of how modification of the sequence of SEQ ID NO: 1 will effect the functional properties of SEQ ID NO: 1. The structure and function of one molecule does not provide guidance as to the structure and function of

other molecules. Therefore, the description of one molecule (SEQ ID NO: 1) is not representative of the claimed genus of homologues, splice, mutant and allelic variants of SEQ ID NO: 1 having unspecified functional activities.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that "appellant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Appellant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court indicated that while Appellants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

In the absence of any real structure-function relationship and in the absence of a representative number of species of the claimed genus, there is insufficient descriptive support for the currently claimed genus of homologues, mutants, allelic and splice variants of SEQ ID NO: 1. Therefore, the written description requirement has not been satisfied for the claims as they are broadly written.

(10) Response to Argument

A. Claim Rejections - 35 USC § 101 (Utility)

Appellants traverse this rejection by stating that the specification discloses that SEQ ID NO: 1 shares a significant identity with a Src homology domain profile.

However, the specification in fact teaches only that SEQ ID NO: 1 has 84% identity with nucleic acid encoding an unknown protein with a Src homology 3 (SH3) domain profile. The specification does not assert that SEQ ID NO: 1 itself encodes f or a protein having a SH3 domain profile. Nor does the specification assert that the protein encoded by SEQ ID NO: 1 has a biological activity that is the same as or similar to the "unknown protein."

Appellants assert that upon reading the specification, one would readily recognize the importance of proteins having SH3 domains, for example in signal transduction.

This argument is not persuasive because the present specification does not in fact teach that proteins having a SH3 domain have signal transduction activity. Most importantly, the specification does not teach that proteins encoded by SEQ ID NO: 1 have signal transduction activity. Even if proteins encoded by SEQ ID NO: 1 were described as having signal transduction activity, such a disclosure would not impart a specific and substantial use for the encoded proteins. Proteins having signal transduction activity constitute a very broad class of proteins, having widely diverse activities and biological effects. A "specific utility" is a utility that is *specific* to the subject matter claimed, as compared with a "general utility" that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real

world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not considered to be substantial utilities. Thus, classification of a nucleic acid as encoding for a protein having any type of signal transduction activity does not establish a specific and substantial use for the nucleic acid.

Appellants cite Sparks et al as teaching that SH3 domains are conserved in a variety of proteins with important roles in signal transduction. It is argued that signal transduction is a specific biological activity that satisfies the requirements of 35 U.S.C. 101.

This argument is not persuasive because, as discussed above, signal transduction covers a wide variety of distinct biological activities and effects and thereby does not constitute a specific and substantial utility. While Sparks teaches that proteins having a SH3 domain may have important biological activities, Sparks acknowledges that such activities are significantly diverse. Sparks (see abstract) teaches that SH3 domains vary with respect to the ligands that they bind and that "the ligand preferences of most SH3 domains and the role of these preferences in regulating SH3-mediated protein-protein interactions remain poorly defined." Sparks states that SH3 domains are able to discern subtle differences in the primary structure of potential ligands, such that "(e)ach SH3 domain selects a set of peptide ligands sharing a distinct consensus motif; these motifs reflect the unique ligand preferences of each SH3 domain" (page 1540). The reference teaches that proteins having SH3 domains may play a role in wide variety of biological activities, including growth factor-mediated activation of ras, stimulation of

PI3K activity, assembly of the phagocyte NADPH oxidase (page 1540). However, the present specification does not identify a particular SH3 domain present in the protein encoded by SEQ ID NO: 1; does not identify a ligand that binds to a SH3 domain of a protein encoded by SEQ ID NO: 1; and does not identify a specific biological activity associated with the binding of a ligand to a SH3 domain of a protein encoded by SEQ ID NO: 1. Thereby, it is maintained that a disclosure that SEQ ID NO: 1 shares 84% identity with a nucleic acid encoding an unknown protein have a SH3 domain profile does not provide a specific and substantial use for the nucleic acid of SEQ ID NO: 1.

Appellants argue that the specification need not disclose what is known to one of ordinary skill in the art. It is asserted that one of skill in the art would understand the importance of signal transduction and would readily appreciate this utility as being substantial.

This argument is also not persuasive because, again, the specification does not clearly contemplate that the proteins encoded by SEQ ID NO: 1 have signal transduction activity. Further, proteins having signal transduction activity constitute a broad genus of compounds, having highly diverse biological activities and effects. Thereby, signal transduction activity does not constitute a specific and substantial activity.

Lastly, Appellants assert that the specification teaches that SEQ ID NO: 1 "may contain promoter regions or partial promoter regions." Pages 23, line 5 to page 30, line 6 of the specification are cited in support of this argument.

These arguments have also been fully considered but are not persuasive. Regarding this asserted utility, the specification generally states: "Another class of agents of the present invention are nucleic acid molecules having promoter regions or partial promoter regions or regulatory elements, particularly those promoter regions or partial promoter regions or regulatory elements located with SEQ ID NO: 1 through SEQ ID NO: 51,470" (page 23). However, the specification does not disclose the identity or location of any particular promoter sequences or regulatory elements in SEQ ID NO: 1. The specification (page 23) states that promoters can include between about 300 bp upstream and about 10kb upstream of the trinucleotide ATG sequence at the start site of a protein coding region. However, present SEQ ID NO: 1 consists of 1093 nucleotides. The specification does not identify the first ATG start site of a protein coding region. However, the first potential ATG start site occurs at nucleotides 22-24 of SEQ ID NO: 1. As such, the nucleic acid of SEQ ID NO: 1 does not appear to include 300 to 10kb upstream sequences that may contain a potential promoter region. Further, the present claims are not limited to those sequences within SEQ ID NO: 1 which have promoter or regulatory activity. The full length molecule of SEQ ID NO: 1 is not itself a promoter or regulatory element. Thereby, Appellants have not established that the full length molecule of SEQ ID NO: 1 can be used as a promoter or a regulatory element.

B. Claim Rejections - 35 USC § 112 (Enablement)

Appellants traverse this rejection by stating that this rejection has been overcome by the arguments provided above regarding utility. However, for the reasons set forth above, it is maintained that the uses asserted for the claimed invention are an object of

study and are not specific, nor substantial. The specification cannot enable or teach one how to use the invention within 35 U.S.C. 112, first paragraph, if there is no patentable utility within 35 U.S.C. 101. Because there is no utility for the claimed invention for the reasons set forth above, it is maintained that the specification has not enabled the claimed invention.

Further, Appellants argue that the cited Whisstock reference teaches that predicting protein structure from a sequence provides "reasonable guesses at function." Appellants state that they have provided a reasonable correlation (84% identity) between the claimed sequence and a protein with a SH3 domain profile. Thereby, Appellants conclude that they have satisfied the legal requirements for a showing of utility.

However, Appellants have not in fact established a clear correlation between the presently claimed nucleic acid of SEQ ID NO: 1 and the nucleic acid set forth in Table 1 (page 92). As discussed above, this table states only that SEQ ID NO: 1 shares 84% identity with nucleic acid encoding an "unknown protein" having a SH3 domain profile. The specification does not teach that SEQ ID NO: 1 itself includes a SH3 domain profile. Thereby, the specification did not clearly contemplate that the protein encoded by SEQ ID NO: 1 has any particular functional activity associated with the presence of a SH3 domain profile. Even if the specification did teach that the protein encoded by SEQ ID NO: 1 included a SH3 domain, the presence of such a domain would not provide sufficient guidance to enable the skilled artisan to predictably use the claimed nucleic acids. As clearly established by the cited Sparks reference, proteins having a SH3

domain bind to distinct ligands and have a wide variety of distinct biological activities. One cannot predict the specific functional activity of a protein based solely on the presence of a SH3 domain. Further, there are no statements in the specification to indicate that the protein encoded by SEQ ID NO: 1 has the same or a similar activity as the "unknown protein." Thereby, a disclosure that the SEQ ID NO: 1 shares 84% identity with a nucleic acid encoding a protein of unknown function does not provide sufficient guidance to enable the skilled artisan to use the claimed nucleic acid for a meaningful purpose. Lastly, it is noted that the present claims are not limited to the nucleic acid of SEQ ID NO: 1. But, rather also encompass variants having 90% to 99% identity with SEQ ID NO: 1. Given the fact that the specification does not disclose a specific activity for SEQ ID NO: 1 and given the unpredictability in the art of determining the effect of nucleotide changes on the function of a protein encoded thereby, it is highly unpredictable as to what would be the activity of a nucleic acid having 90-99% activity with SEQ ID NO: 1. Thus, it is maintained that undue experimentation would also be required to make and use nucleic acids having 90-99% identity with SEQ ID NO: 1.

C. Claim Rejections - 35 USC § 112 (Written Description)

Appellants traverse this rejection by stating that the specification provides the chemical formula of SEQ ID NO: 1 and this chemical formula clearly distinguishes molecules in the claimed genus from molecules not in the claimed genus. It is asserted that modifications in the sequence of SEQ ID NO: 1 are readily envisioned by one of ordinary skill in the art and "disclosed throughout the specification."

These arguments have been fully considered but are not persuasive. The specification does not in fact disclose a single nucleic acid variant of SEQ ID NO: 1. Rather, the specification discloses only a nucleic acid consisting of SEQ ID NO: 1. The disclosure of a single nucleic acid of SEQ ID NO: 1 does not constitute a representative number of species within the broadly claimed genus of nucleic acids having 90 to 99% identity with SEQ ID NO: 1 and having any biological activity or function.

Appellants assert that the members of the claimed genus share the common feature of SEQ ID NO: 1 and thereby one of ordinary skill in the art would recognize that Appellants were in possession of nucleic acids having between 90% and 100% identity with SEQ ID NO: 1. It is stated that by describing the common structural feature of SEQ ID NO: 1, Appellants have satisfied at least, the *Eli Lilly* test for written description.

These arguments are also not persuasive. The claimed genus of nucleic acids do not in fact share the common structure of SEQ ID NO: 1. Rather, the claimed genus of nucleic acids differ from SEQ ID NO: 1 at up to 1 out of every 10 nucleotide positions. Further, the claimed nucleic acids do not share a common functional activity because neither the specification nor the claims set forth a specific functional activity for the claimed homologues, mutant and allelic variants of SEQ ID NO: 1. The specification does not describe the location or identity of nucleotides which may be varied within SEQ ID NO: 1, and does not describe the functional activity associated with such variants. The specification also does not disclose any specific variants of SEQ ID NO: 1 which have a functional activity or biological role distinct from that of SEQ ID NO: 1. Modification of a nucleic acid sequence by 1 to 10% can significantly alter the functional

activity of the nucleic acid and the protein encoded thereby. The genus of nucleic acids claimed is large and variable, and potentially includes nucleic acids encoding for proteins having diverse biological functions. The specification discloses only one member of the claimed genus, i.e., SEQ ID NO: 1. This disclosure is not sufficient to place one of skill in the art in possession of a representative number of molecules having the varied attributes and features of the species within the claimed genus. Adequate written description requires more than a mere statement that such nucleic acids are part of the invention and reference to a potential method for identification. The particular nucleic acids are required. Accordingly, it is maintained that the written description requirements have not been adequately met for the broadly claimed genus of homologues, splice, mutant and allelic variants of SEQ ID NO:1.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Carla Myers/
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Conferees:

Joseph Woitach
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